

hbd-21

Bill No. HB 2013

Amendment No. ____ (for drafter's use only)

<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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ORIGINAL STAMP BELOW

Representative(s) Kelly offered the following:

Amendment (with title amendment)

On page 219, between lines 29 and 30, of the bill

insert:

Section 169. Subsection (3) of section 499.012,
Florida Statutes, is amended to read:

499.012 Wholesale distribution; definitions; permits;
general requirements.--

(3)~~(a)~~ A person that engages in wholesale distribution
of prescription drugs in this state must have a wholesale
distributor's permit issued by the department, except as noted
in this section. Each establishment must be separately
permitted except as noted in this subsection.

(a) A separate establishment permit is not required
when a permitted prescription drug wholesaler consigns a
prescription drug to a pharmacy that is permitted under
chapter 465 and located in this state, provided that:

1. The consignor wholesaler notifies the department in
writing of the contract to consign prescription drugs to a

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1 pharmacy along with the identity and location of each
2 consignee pharmacy;

3 2. The pharmacy maintains its permit under chapter
4 465;

5 3. The consignor wholesaler, which has no legal
6 authority to dispense prescription drugs, complies with all
7 wholesale distribution requirements of s. 499.0121 with
8 respect to the consigned drugs and maintains records
9 documenting the transfer of title or other completion of the
10 wholesale distribution of the consigned prescription drugs;

11 4. The distribution of the prescription drug is
12 otherwise lawful under this chapter and other applicable law;

13 5. Open packages containing prescription drugs within
14 a pharmacy are the responsibility of the pharmacy, regardless
15 of how the drugs are titled; and

16 6. The pharmacy dispenses the consigned prescription
17 drug in accordance with the limitations of its permit under
18 chapter 465 or returns the consigned prescription drug to the
19 consignor wholesaler. In addition, a person who holds title to
20 prescription drugs may transfer the drugs to a person
21 permitted or licensed to handle the reverse distribution or
22 destruction of drugs. Any other distribution by and means of
23 the consigned prescription drug by any person, not limited to
24 the consignor wholesaler or consignee pharmacy, to any other
25 person is prohibited.

26 (b) A wholesale distributor's permit is not required
27 for the one-time transfer of title of a pharmacy's lawfully
28 acquired prescription drug inventory by a pharmacy with a
29 valid permit issued under chapter 465 to a consignor
30 prescription drug wholesaler, permitted under this chapter, in
31 accordance with a written consignment agreement between the

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1 pharmacy and that wholesaler if: the permitted pharmacy and
2 the permitted prescription drug wholesaler comply with all of
3 the provisions of paragraph (3)(a) and the prescription drugs
4 continue to be within the permitted pharmacy's inventory for
5 dispensing in accordance with the limitations of the pharmacy
6 permit under chapter 465. A consignor drug wholesaler may not
7 use the pharmacy as a wholesale distributor through which it
8 distributes the legend drugs to other pharmacies. Nothing in
9 this section is intended to prevent a wholesale drug
10 distributor from obtaining this inventory in the event of
11 nonpayment by the pharmacy.

12 (c)~~(b)~~ The department shall require information from
13 each wholesale distributor as part of the permit and renewal
14 of such permit, as required under s. 499.01.

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16 (Renumber subsequent section)

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19 ===== T I T L E A M E N D M E N T =====

20 And the title is amended as follows:

21 On page 13, line(s) 15,

22

23 after the semicolon insert:

24 amending s. 499.012, F.S.; clarifying and
25 providing for additional wholesale distribution
26 exceptions;

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